JHS

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PHILIP YEATTS; ED ANDRE; ANNETTE MANNING; MARY J. MCPARTLAN HURSON; LARRY WICKER; JOHN MARSHALL; JOHN GROVER; SHARON ANDERSON; DIANA CABCABIN; TAMMY JACKSON; CAROLYN SAMPSON; TED MANN; and RICHARD ANDERSON Plaintiffs, v. SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; GLAXOSMITHKLINE, LLC; GLAXOSMITHKLINE HOLDINGS, INC.; SANOFI-AVENTIS, U.S., LLC; AVANTOR PERFORMANCE MATERIALS; GRÜNENTHAL GMBH; and GRÜNENTHAL U.S.A., Defendants.	11 6711 CASE NO.:_____

NOTICE OF REMOVAL

Pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, Defendants GlaxoSmithKline LLC, formerly known as SmithKline Beecham Corporation and GlaxoSmithKline Holdings (Americas) Inc. ("the GSK Defendants")[1] hereby give notice of removal of this action, entitled *Yeatts, et al v. SmithKline Beecham Corp., et al.*, Case No. 111003316, from the First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia County, Civil Trial Division, to the United States District Court for the Eastern District of Pennsylvania.

As grounds for removal, the GSK Defendants state as follows:

[1] Named Defendant "SmithKlineBeecham Corporation d/b/a/ GlaxoSmithKline" is no longer a viable entity. *See* ¶ 21, infra.

I. REMOVAL TO THIS JUDICIAL DISTRICT IS PROPER AND TIMELY

1. Plaintiffs, thirteen individuals, commenced this action in the First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia County, Civil Trial Division, by filing a Complaint on October 25, 2011, at October Term 2011, Case ID 111003316 (the "Philadelphia County Action"), naming as defendants SmithKline Beecham Corporation d/b/a/ GlaxoSmithKline ("SKB"); GlaxoSmithKline LLC ("GSK LLC"); GlaxoSmithKline Holdings, LLC ("GSK Holdings"); Sanofi-Aventis, U.S., LLC ("Sanofi"); Avantor Performance Materials, Inc. ("Avantor"); Grünenthal GmbH; and Grünenthal U.S.A. (collectively, "Defendants"). Pursuant to 28 U.S.C. § 1446(a), a true and legible copy of the Complaint is attached as **Exhibit A.**

2. Upon information and belief, Defendant GlaxoSmithKline LLC is the only Defendant who has been served with the Complaint. While GlaxoSmithKline Holdings (Americas) Inc., has not yet been served with the Complaint, it files this removal jointly with GlaxoSmithKline LLC. The consent of the unserved Defendants to this removal is not required. *See Lewis v. Rego Co.*, 757 F.2d 66, 68-69 (3d Cir. 1985) (finding an exception to the consent rules where a defendant has not been served at the time of removal); *Landman v. Borough of Bristol*, 896 F. Supp. 406, 409 (E.D.Pa. 1995) ("A co-defendant need not be joined when the co-defendant has not been served .... ").

3. The Complaint was filed on October 25, 2011, less than 30 days prior to the date of this Notice of Removal, so this Notice of Removal is timely filed pursuant to 28 U.S.C. § 1446(b).

4. No further pleadings have been filed, and no proceedings have yet occurred in the Philadelphia County Action.

5. Defendant bases removal on diversity jurisdiction pursuant to 28 U.S.C. §§ 1332, 1441, and 1446.

II. STATUTORY BASIS FOR JURISDICTION

6. Removal of this action is proper under 28 U.S.C. § 1441. The Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) as it is a civil action between citizens of different states in which the amount in controversy exceeds the sum of $75,000.00, exclusive of interest and costs.

A. There is Complete Diversity Between the Parties.

7. Plaintiff Philip Yeatts is a citizen of the State of Texas. *See* Docket Sheet, *Yeatts v. SmithKline Beecham Corp., et al.*, a true and legible copy of which is attached as **Exhibit B**.

8. Plaintiff Ed Andre is a citizen of the State of Kentucky. *See* Ex. B.

9. Plaintiff Annette Manning is a citizen of the State of New Mexico. *See* Ex. B.

10. Plaintiff Mary McPartlan Hurson is a citizen of the State of New York. *See* Ex. B.

11. Plaintiff Larry Wicker is a citizen of the State of Georgia. *See* Ex. B.

12. Plaintiff John Marshall is a citizen of the State of Louisiana. *See* Ex. B.

13. Plaintiff John Grover is a citizen of the State of Florida. *See* Ex. B.

14. Plaintiff Sharon Anderson is a citizen of the State of Wisconsin. *See* Ex. B.

15. Plaintiff Diana Cabcabin is a citizen of the State of California. *See* Ex. B.

16. Plaintiff Tammy Jackson is a citizen of the State of Texas. *See* Ex. B.

17. Plaintiff Carolyn Sampson is a citizen of the State of Minnesota. *See* Ex. B.

18. Plaintiff Ted Mann is a citizen of New South Wales, Australia. *See* Ex. B.

19. Plaintiff Richard Anderson is a citizen of the State of New York. *See* Ex. B.

20. Under 28 U.S.C. § 1332(c)(1), "a corporation shall be deemed to be a citizen of any State by which it has been incorporated and of the State where it has its principal place of business ...." For purposes of diversity jurisdiction, the citizenship of an LLC is that of its members. *Zambelli Fireworks Mfg. Co., Inc. v. Wood*, 592 F.3d 412, 418-19 (3d Cir. 2010).

21. Named Defendant SKB was a Pennsylvania corporation that on October 27, 2009 converted into GlaxoSmithKline LLC, a limited liability company organized under Delaware law. *See* Declaration of Julian Heslop, a true and legible copy of which is attached hereto as **Exhibit C**, at ¶¶ 4-11. Accordingly, the citizenship of GlaxoSmithKline LLC is addressed below.

22. Defendant GSK LLC is a limited liability company organized under Delaware law. The sole member of GlaxoSmithKline LLC is GlaxoSmithKline Holdings (Americas) Inc. Heslop Decl., ¶ 11. GlaxoSmithKline Holdings (Americas) Inc. is a Delaware corporation with its principal place of business in Wilmington, Delaware. Heslop Decl., ¶ 12; see also *White v. SmithKline Beecham Corp.*, No. 2:10-cv-2241, 2010 U.S. Dist. LEXIS 79520, *8-9 (E.D. Pa. Aug. 6, 2010)(holding that GSK Holdings' principal place of business is in Delaware, and denying Plaintiffs' motion to remand the action to the Philadelphia Court of Common Pleas); *Hoch v. Eli Lilly & Co.*, 736 F. Supp.2d 219, 221 (D. D.C. 2010) (holding that GSK LLC is a citizen of Delaware).2 Defendant GSK LLC is, therefore, a citizen of the State of Delaware.

23. Defendant GSK Holdings is improperly identified in Plaintiffs' Complaint and is in fact GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its principal place of business in Wilmington, Delaware. Defendant GSK Holdings is, therefore, a citizen of the State of Delaware.

---

[2] The Eastern District of Pennsylvania has reached differing conclusions on the citizenship of GSK LLC. After Judge Mary McLaughlin concluded that GSK LLC was a Delaware citizen in *White*, Judge Timothy Savage allowed the parties to conduct additional jurisdictional discovery and subsequently remanded several consolidated cases in the Paxil® litigation, based on his conclusion that GSK LLC is a citizen of Pennsylvania. *See Brewer v. SmithKline Beecham Corp.*, No. 2:10-cv-04443-GP, 2011 U.S. Dist. LEXIS 31149 (E.D. Pa. Mar. 24, 2011). However, the *Brewer* ruling fashioned a new test for determining the citizenship of limited liability companies, which is inconsistent with controlling Third Circuit and Supreme Court authority. GSK was precluded from seeking review of the *Brewer* decision under 28 U.S.C. § 1447(d), but respectfully submits that *Brewer* was incorrectly decided.

24. Defendant Sanofi is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New Jersey. Defendant Sanofi is, therefore, a citizen of the States of Delaware and of New Jersey.

25. Defendant Avantor is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Pennsylvania. Defendant Avantor is, therefore, a citizen of the States of New Jersey and Pennsylvania.

26. Defendant Grünenthal GmbH is a German corporation registered in Aachen, Germany. Defendant Grünenthal GmbH is, therefore, a citizen of Germany.

27. Defendant Grünenthal U.S.A. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New Jersey. Defendant Grünenthal U.S.A. is, therefore, a citizen of the States of Delaware and New Jersey.

28. Because Plaintiffs and Defendants are citizens of different countries and states, there is complete diversity.

B. The Amount in Controversy Requirement is Met.

29. As noted, there are thirteen Plaintiffs in this case.

30. Each Plaintiff alleges that they suffer from serious and/or multiple birth defects related to their mothers' ingestion of thalidomide during pregnancy. *See, e,g.*, Ex. A at ¶¶ 9 - 76.

31. Plaintiffs request damages including past, present, and future economic damages; compensatory damages, including damages for physical injuries, pain and suffering, mental anguish, emotional distress, embarrassment, shame, anguish, anxiety, and loss of enjoyment of life; general damages for alleged wrongful conduct; reasonable costs, including attorneys' fees; prejudgment interest and postjudgment interest; punitive damages; and past, present, and future special damages, including medication, medical expenses, rehabilitation expenses, assisted living, and nursing care. Id., ¶¶ 344-45.

32. Given the nature and extent of Plaintiffs' alleged injuries and damages, Plaintiffs' Complaint places at issue more than $75,000, exclusive of interest and costs. *See Angus v. Shiley, Inc.*, 989 F.2d 142, 146 (3d Cir. 1993) ("the amount in controversy is not measured by the low end of an open-ended claim, but rather by a reasonable reading of the value of the rights being litigated").

33. Plaintiffs' claim for damages therefore exceeds the requisite amount in controversy for purposes of diversity jurisdiction under 28 U.S.C. § 1332(a).

C. Removal is Proper Because No Forum Defendant Has Been Served With Process.

34. Pursuant to 28 U.S.C. § 1441(b), this action is removable because no party in interest properly joined and served as a defendant is a citizen of the Commonwealth of Pennsylvania, the state in which this action was brought (a "forum defendant"). *See* 28 U.S.C. § 1441(b) (providing that non-federal question cases "shall be removable only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which the action is brought") (emphasis added).

35. Upon information and belief, no forum Defendant has been served. Removal is proper where there is complete diversity, but no forum defendant has yet been served. Relying on the language of Section 1441 (b), in *Copley v. Wyeth, Inc.*, the United States District Court for the Eastern District of Pennsylvania denied plaintiffs motion for remand, where, as here, a non-forum defendant had removed the action when the alleged forum defendant had not been properly joined and served. *Copley v. Wyeth, Inc.*, Civil Action No. 09-722, 2009 WL 1089663 (E.D. Pa. Apr. 22, 2009); *see also Vanderwerf v. GlaxoSmithKline,* Civil Action No. 05-1315, 2005 WL 6151369, at *1 (E.D. Pa. May 5, 2005); *Hutchins v. Bayer Corp.*, C.A. No. 08-640-JJF-LPS, 2009 WL 192468, at *11 (D. Del. Jan. 23, 2009); *Thomson v. Novartis Pharms. Corp.*, No. 06-6280 (JBS), 2007 WL 1521138, at *4 (D. N.J. May 22, 2007).

36. In the present case, because Plaintiffs have not served any forum defendant, any such defendant's purported residence in Pennsylvania is not an impediment to removal under 28 U.S.C. § 1441(b).

D. Plaintiffs' Allegations of Certain Defendants' Pennsylvania Citizenship Do Not Defeat Removal.

37. Plaintiffs allege that SKB is a Pennsylvania corporation with its principal place of business in Pennsylvania; that GSK LLC has its principal place of business in Pennsylvania; that GSK Holdings has its principal place of business in Pennsylvania; and that Avantor has its principal place of business in Pennsylvania. See Ex. A ¶¶ 3, 4, 5, 7.

38. As set forth above, SKB converted to GSK LLC on October 27, 2009. See ¶ 10 supra; see also Heslop Decl., ¶ 7-10. The citizenship of GSK LLC is determined by the citizenship of its members, and its sole member is GSK Holdings. See ¶ 9 supra; see also Zambelli, 592 F.3d at 418-19. GSK Holdings is a Delaware corporation with its principal place of business in Wilmington, Delaware. Heslop Decl., ¶ 13. Therefore both GSK LLC and GSK Holdings are citizens of Delaware, not Pennsylvania.

39. Alternatively, the GSK Defendants have been fraudulently joined for the sole purpose of attempting to defeat Defendants' right to have this case removed to, and heard by, a federal court. The Complaint does not allege that either plaintiff was harmed by any drug sold, distributed, marketed or manufactured by any GSK Defendant, and the Complaint fails to state any conceivably viable claim against the GSK Defendants.

40. Avantor is a citizen of both Pennsylvania and New Jersey, because it is incorporated in New Jersey and has its principal place of business in New Jersey.

41. Because Avantor has not yet been served, its status as a forum Defendant does not make removal improper. *See Copley v. Wyeth, Inc.*, Civil Action No. 09-722, 2009 WL 1089663 (E.D. Pa. Apr. 22, 2009); *see also Vanderwerf v. GlaxoSmithKline,* Civil Action No. 05-1315, 2005 WL 6151369, at *1 (E.D. Pa. May 5, 2005); *Hutchins v. Bayer Corp.*, C.A. No. 08-640-

JJF-LPS, 2009 WL 192468, at *11 (D. Del. Jan. 23, 2009); *Thomson v. Novartis Pharms. Corp.*, No. 06-6280 (JBS), 2007 WL 1521138, at *4 (D. N.J. May 22,2007).

42. Alternatively, Avantor has been fraudulently joined for the sole purpose of attempting to defeat Defendants' right to have this case removed to, and heard by, a federal court. The Complaint does not allege that either plaintiff was harmed by any drug sold, distributed, marketed or manufactured by Avantor, and the Complaint fails to state any conceivably viable claim against Avantor.

43. Because no Defendant against whom a colorable cause of action has been alleged and who has been served is a citizen of the Commonwealth of Pennsylvania, removal is proper. *See* 28 U.S.C. § 1441(b) (Any diversity action shall be removable "only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.").

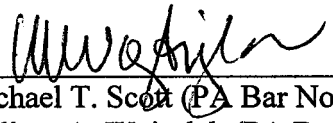
III. NOTICE IS BEING SENT TO PLAINTIFFS AND FILED IN STATE COURT

44. Pursuant to 28 U.S.C. § 1446(d), Defendants shall give Plaintiffs written notice of the filing of this Notice of Removal.

45. Pursuant to 28 U.S.C. § 1446(d), Defendants shall file the written notice of the filing of this Notice of Removal with the Prothonotary of the Court of Common Pleas of Philadelphia County, Pennsylvania, attaching as Exhibit A thereto a copy of this Notice of Removal and the documents attached to this Notice of Removal.

WHEREFORE, the Defendants hereby give notice that the above-entitled state court action, formerly pending in the First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia County, Civil Trial Division, has been removed to the United States District Court for the Eastern District of Pennsylvania.

Respectfully submitted,



Michael T. Scott (PA Bar No. 23882)
Melissa A. Wojtylak (PA Bar No. 78354)
REED SMITH LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, Pennsylvania 19103
(215) 851-8100

Attorneys for Defendants GlaxoSmithKline LLC, formerly known as SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, and GlaxoSmithKline Holdings (Americas) Inc.

Dated: October 27, 2011

CERTIFICATE OF SERVICE

The undersigned hereby certifies that Defendants GlaxoSmithKline LLC's and GlaxoSmithKline Holdings (Americas) Inc.'s Notice of Removal has been forwarded to the Clerk's Office this 27th day of October, 2011. A copy of the foregoing has also been sent via electronic mail and U.S. Mail on the following:

Jeffrey L. Kodroff, Esq. Mary Ann Giorno, esq. Spector, Roseman, Kodroff & Willis, P.C. 1818 Market Street, Suite 2500 Philadelphia, PA 19103 *Attorneys for Plaintiff*	Steve W. Berman, Esq. Nick Styant-Browne, Esq. Craig R. Spiegel, Esq. Hagens Berman Sobol Shapiro LLP 1918 Eighth Avenue, Suite 3300 Seattle, WA 98101 *Attorneys for Plaintiff*
Kay Gunderson Reeves, Esq. Gordon & Reeves Law, LLP 10000 N. Central Expressway, Suite 400 Dallas, TX 75231 *Attorneys for Plaintiffs*	Sanofi-Aventis US LLC 55 Corporate Drive Bridgewater, NJ 08807
Avantor Performance Materials 3477 Corporate Parkway, Suite 200 Center Valley, PA 18034	Grünenthal GMBH 52099 Aachen Germany 52099
Grünenthal USA One Pluckemin Way Bedminster, NJ 07921	

Melissa A. Wojtylak

EXHIBIT A

HAGENS BERMAN SOBOL SHAPIRO LLP
By: Steve W. Berman
By: Nick Styant-Browne
By: Craig R. Spiegel
1918 Eighth Ave., Suite 3300
Seattle, WA 98101

GORDON & REEVES, LLP
By: Peter Gordon, Esquire
By: Kay Gunderson Reeves, Esquire
10000 North Central Expressway, Suite 400
Dallas, TX 75231

PHILIP YEATTS; ED ANDRE; ANNETTE MANNING; MARY J. MCPARTLAN HURSON; LARRY WICKER; JOHN MARSHALL; JOHN GROVER; SHARON ANDERSON; DIANA CABCABIN; TAMMY JACKSON; CAROLYN SAMPSON; TED MANN; and RICHARD ANDERSON,	**PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION**
PLAINTIFFS,	**TERM:**
v.	**CIVIL ACTION NO.:**
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE; GLAXOSMITHCLINE, LLC; GLAXOSMITHCLINE HOLDINGS, INC.; SANOFI-AVENTIS, U.S., LLC; AVANTOR PERFORMANCE MATERIALS; GRÜNENTHAL GMBH; and GRÜNENTHAL U.S.A.,	**COMPLAINT**
DEFENDANTS.	**JURY TRIAL DEMANDED**

NOTICE TO PLEAD

NOTICE
You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within

ADVISO
Le han demandado a used en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de

twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER. IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED OR NO FEE.

Lawyer Referral Service
Philadelphia Bar Association
1101 Market St., 11th Floor
Philadelphia, PA 19107
(215) 238-6338

plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte pueda decider a favor del demandante y require que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATEMENTE, SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA A LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ESTA OFICINA LO PUEDE PROPORCIONAR CON INFORMACION ACERCA DE EMPLEAR A UN ABOGADO. SI USTED NO PUEDE PROPORCIONAR PARA EMPLEAR UN ABAGADO, ESTA OFICINA PUEDE SER CAPAZ DE PROPORCIONARLO CON INFORMACION ACERCA DE LAS AGENCIAS QUE PUEDEN OFRECER LOS SERVICOS LEGALES A PERSONAS ELEGIBLES EN UN UHONORARIO REDUCIDO NINGUN HONORARIO.

Lawyer Referral Service
Philadelphia Bar Association
1101 Market St., 11th Floor
Philadelphia, PA 19107

LOCAL COUNSEL
By: Jeffrey L. Kodroff (PA Bar No. 55780)
SPECTOR, ROSEMAN, KODROFF & WILLIS, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Attorneys for Plaintiffs

HAGENS BERMAN SOBOL SHAPIRO LLP
By: Steve W. Berman
By: Nick Styant-Browne
By: Craig R. Spiegel
1918 Eighth Ave., Suite 3300
Seattle, WA 98101

GORDON & REEVES, LLP
By: Peter Gordon, Esquire
By: Kay Gunderson Reeves, Esquire
10000 North Central Expressway, Suite 400
Dallas, TX 75231

ROBERT MURRAY and DIANE KESSLER,	) **PHILADELPHIA COUNTY**
	) **COURT OF COMMON PLEAS**
PLAINTIFFS	) **TRIAL DIVISION**
	)
v.	) **TERM:**
	)
SMITHKLINE BEECHAM CORPORATION	) **CIVIL ACTION NO.:**
d/b/a GLAXOSMITHKLINE;	)
GLAXOSMITHCLINE, LLC;	) **COMPLAINT**
GLAXOSMITHCLINE HOLDINGS, INC.;	)
SANOFI-AVENTIS, U.S., LLC;	) **JURY TRIAL DEMANDED**
AVANTOR PERFORMANCE MATERIALS;	)

GRÜNENTHAL GMBH; and	)
GRÜNENTHAL U.S.A.,	)
	)
DEFENDANTS.	)

TABLE OF CONTENTS

I. INTRODUCTION

1. Plaintiffs suffer from severe birth defects caused by thalidomide, a drug given to their mothers in early pregnancy as a treatment for morning sickness. Until less than two years ago, Plaintiffs did not discover (and could not reasonably have discovered) that thalidomide caused their injuries. Defendants' fraudulent concealment of their wrongdoing in the development of thalidomide – and its marketing, testing and distribution in the United States – tolled the limitations period for Plaintiffs' claims until the truth about Defendants' wrongful acts became known within the last year.

2. Defendants told the public and Congress that thalidomide-caused birth defects that permeated Europe couldn't and didn't happen in the United States because the drug was available only on a limited "clinical trial" distribution.

3. But evidence that only recently came to light based on extraordinary investigative efforts, reveals that the story that thalidomide did not cause thalidomide injuries in the United States was not the truth. Instead, it was a carefully constructed lie sold to the public to protect Defendants from having to accept responsibility for what they had done.

4. And what they had done was nothing short of creating every family's nightmare by virtue of babies dying in infancy due to thalidomide, or surviving with birth defects, some so severe as to shock care-givers and family members.

5. The truth is that Richardson-Merrell launched a massive *marketing* effort, not a research effort, or "clinical trial," distributing at least 2.5 million doses of thalidomide in the U.S. That marketing effort targeted those most vulnerable to their destructive drug – hospital

OB-GYN departments and pregnant women. None of the mothers-to-be, who innocently took thalidomide under doctor's orders, knew that they were taking a drug deadly to adult laboratory animals. None of these mothers knew that they were taking a drug that had never been tested on any pregnant animal before being given to unsuspecting pregnant women in 46 countries, including the United States.

6. And none of them knew they were taking a drug that by 1956 had caused birth defects in a baby born to the wife of at least one Grünenthal employee who had taken thalidomide during her pregnancy, a birth defect risk that defendant Smith, Kline & French learned about firsthand by 1958 but did not reveal. Instead of revealing that thalidomide could cause birth defects so that warnings could be given and thousands of families spared a lifetime of heartache, some Defendants actively concealed the truth and marketed thalidomide as "safe" and "harmless," particularly for pregnant women. Smith, Kline & French went so far as to lie to Congress about what it knew about the danger thalidomide posed to pregnant women.

7. In the decades that have passed, each Defendant has continued to cover up the tragic truth about what Defendants knew and did – denying justice to their many victims.

8. Plaintiffs in this action have lived for decades with injuries caused by thalidomide. Now armed with the truth for the first time, they seek damages resulting from defendants' negligence, fraud, negligent misrepresentation, negligent hiring, conspiracy and alter ego in that:

- All defendants were negligent with respect to the manufacture, design, testing, distribution, marketing and sale of thalidomide.

- The Grünenthal Defendants and Sanofi-Aventis Defendants fraudulently misrepresented to patients, "clinical trial" subjects, physicians and clinical investigators, and the public that there had been no hint or suspicion that thalidomide could cause birth defects before news of the European tragedy regarding thalidomide and birth defects came to light in November 1961. They fraudulently concealed the fact that they knew that thalidomide had actually caused birth defects in babies born to women taking thalidomide years before that. By 1955, all Defendants knew or should have known that thalidomide posed a birth-defect risk.
- Smith, Kline & French fraudulently concealed and misrepresented material facts relating to its use and distribution of thalidomide and its knowledge of the birth defect hazard thalidomide posed to pregnant women.
- Grünenthal breached its duty of care by failing to properly hire and supervise those employees that were responsible for development of thalidomide. The Grünenthal Defendants breached this duty when they hired and retained officers, directors, and employees who were known to have actively participated in the Nazi prison camp experimentation programs, racial hygiene programs, and forced deportation and "Germanization" programs, including persons who had been charged and prosecuted as Nazi war criminals for their actions during WWII. It was known or knowable, and was reasonably foreseeable that such persons would not exercise the care required of a pharmaceutical manufacturer, designer and

seller/distributor when making decisions about product testing, product marketing, and the provision of adequate safety information.

- All Defendants acted in concert and engaged in a conspiracy to conceal material adverse facts regarding the marketing, distribution and dangers of thalidomide when used by pregnant women.

II. THE PARTIES

A. Plaintiffs

1. Philip Yeatts

9. Philip Yeatts was born in Brownfield, Texas, on September 18, 1962. Philip was born with multiple serious birth defects. His right leg and foot are missing. His right arm ends above the elbow, and he has no fingers on his right hand. He was born with a severely cleft palate and a deformed tongue. He later learned that he has a curved spine, and he had to undergo surgery to drop his left testicle.

10. His mother, Jerry Sue, suffered from violent morning sickness during her pregnancy and sought treatment from her physician, Dr. Noah Stone. Dr. Stone gave her medication for her morning sickness but did not tell her the name of the medication. Jerry Sue also recalls that though Dr. Stone performed at least one sonogram on her during her pregnancy, he would not discuss the results with her. Jerry Sue does not recall seeing Dr. Stone again after delivering Philip, though she may have had one more office visit with him. Multiple babies delivered by Dr. Stone during this time period suffered from birth defects, and several died, including a baby born to Jerry Sue's friends.

11. Dr. Stone denies that he gave Jerry Sue thalidomide. He never told the Yeatts family that Philip's birth defects were or might be related to medication that he prescribed. He denies remembering Philip or anything about thalidomide, and denies that any medical records for Philip exist.

12. Jerry Sue believes that her husband's parents hired an investigator to gather additional facts, and understands that this investigator confirmed that she had been given thalidomide, although he informed the family that "no laws had been broken."

13. Unknown to the Yeatts family, Philip's aunt, Betty Timmons, wrote a letter to a *Washington Post* reporter, Morton Mintz, shortly after Philip was born, telling him that Dr. Stone denied giving thalidomide to Jerry Sue. Mrs. Timmonds asked Mr. Mintz whether it was possible to obtain a list of doctors who had been provided thalidomide by Richardson-Merrell. Mr. Mintz forwarded Mrs. Timmonds' letter to the FDA, which had asked Richardson-Merrell for such a list in February 1961. Though the agency knew that at least 63 Texas doctors had received thalidomide and that Richardson-Merrell's records of thalidomide disbursements were unreliable, the agency relied on Richardson-Merrell's previous representation that no physicians in "Tahoka, Texas" had been provided with thalidomide, and declined to assist Mrs. Timmonds. To this day, the FDA refuses to disclose the list of physicians to whom Richardson-Merrell provided thalidomide.

14. The predominant medical view has for decades held that thalidomide did not cause the types of unilateral and asymmetrical limb reduction from which Philip suffers. Defendants will make that claim in this case. In fact, there are no representative, controlled studies

documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including Philip's injuries. Only recently available studies published in medical and scientific journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, Philip can now allege that his injuries were caused by thalidomide.

2. Plaintiff Ed Andre

15. Plaintiff Ed Andre was born in Wheeling, West Virginia, on February 2, 1957. He was born with serious birth defects, including two clubbed feet, very knocked knees, very short legs, and missing bones in his left leg. His left hip lacks a ball and socket, so his femur is in direct contact with his hip bone. He is abnormally short, his legs were very twisted at birth, and his left leg was eventually amputated below the knee, one of many surgeries he underwent in his life. He has only four toes on each foot and three fingers and a thumb on his right hand. Ed also has a curved spine and suffers severe coccyx pain due to his malformed skeleton.

16. Ed's mother, Nancy, suffered from serious morning sickness and extreme stress during her pregnancy. She consulted her doctor, who gave her samples of thalidomide in his office, describing it as a new drug from Germany that was not on the market yet. Her father, a pharmacist, had never heard of thalidomide. Her doctor never told her that thalidomide was experimental or that no reproductive safety tests had been conducted.

17. After Ed's birth, his father went in search of the doctor who had given Nancy thalidomide, but that doctor had left town and the family was unable to locate him. The drug was given to Nancy in the office, and there was no record made of its administration.

18. When he was about 10 to 12 years old, Ed and his father discussed the cause of his birth defects, and Ed's father told him that his mother had taken thalidomide while pregnant with him. Neither Ed nor his family knew the names of any companies responsible for its distribution and could not find the doctor who did know. With no clues to follow, Ed was left with no understanding of what it meant to be a thalidomider and no idea who was responsible for developing and distributing the drug. Though during his adult life, he and his doctors acknowledged that his injuries appeared to be thalidomide-related, Ed could not obtain confirmation of that because the medical records were not available. And the publicly available information about thalidomide's distribution in the U.S. did not support the conclusion that a woman in the U.S. could have obtained thalidomide in 1956, the year Nancy Andre became pregnant with Ed. Richardson-Merrell has maintained that it did not start to distribute thalidomide in the United States until 1959. Smith, Kline & French concealed that it had conducted its own human clinical trial in 1955-1957.

19. In the spring of 2011, Ed's mother, Nancy, saw a small notice in a Cincinnati paper seeking information from women who had been prescribed thalidomide. She responded to that notice, learning for the first time facts about the companies that were responsible for the distribution of thalidomide in this country and about their conduct. She also learned for the first time that thalidomide was, indeed, available in the U.S. in 1956 due to the Smith, Kline &

French clinical trial. Armed with this knowledge, Ed can now allege that his injuries were caused by thalidomide.

3. Plaintiff Annette Manning

20. Plaintiff Annette Manning was born in Green Bay, Wisconsin, on November 17, 1960. She suffers from multiple birth defects. Her left arm ends just past the elbow. She has no fingers but only small buds where fingers should be. She has been unable to conceive children and has developed symptoms of peripheral neuropathy. No doctor has ever told Annette or her mother that her injuries were or could have been caused by thalidomide. Instead, the doctors told them that a certain number of children are born with birth defects for unexplained reasons, and that Annette was just unlucky in that regard.

21. In recent years, a nurse casually remarked to Annette that she might be a thalidomide baby. Annette asked her mother, Beverly, whether she had ever taken the drug, and learned that she had. During her pregnancy, Beverly suffered from morning sickness and sought treatment from her physician, Dr. Grendel. Beverly recalls that he provided her with samples of medication in an envelope. While Beverly rarely takes medication of any sort, she took the thalidomide provided to her for a short time during her pregnancy.

22. There was no printed label or other writing on the packaging, but Dr. Grendel wrote the word "thalidomide" on the envelope. Beverly did not see him make a written note in her medical record indicating that he had given her the drug. It is now known that Richardson-Merrell assigned at least one of its "detailmen" to promote thalidomide in Wisconsin.

23. When Beverly awoke after delivering Annette, she realized that she was still in the delivery room, alone. Because she was suffering from laryngitis, Beverly was unable to call anyone. Eventually, she was taken to a regular hospital room but had still not seen her baby. More than eight hours passed before Dr. Grendel visited Beverly to discuss Annette's condition and before he informed her that although Annette's eyes, nose and ears were normal, her left arm and hand were not. Beverly later learned that Dr. Grendel had left the hospital for several hours after delivering Annette, because she was the second malformed baby he had delivered in a short time period. Dr. Grendel retired from his practice soon thereafter.

24. Though her father insisted that baby Annette be sent away, Beverly refused. Her husband soon left the family, and Beverly raised Annette on her own.

25. To date, no doctor has ever told Annette that her injuries were caused by thalidomide. The predominant medical view has held for decades that unilateral and asymmetrical limb reduction defects like Annette's are not caused by thalidomide exposure. Defendants will make that claim in this case. In fact, there are no representative, controlled studies documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including Annette's injuries. Only recently available studies published in medical and scientific journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, Annette can now allege that her injuries were caused by thalidomide.

4. Plaintiff Mary J. McPartlan Hurson

26. Plaintiff Mary J. McPartlan Hurson was born in New York City on July 30, 1960. She suffers from severe birth defects. She was born with no left hand and a malformed left arm that extends only about six inches beyond the elbow, ending at a hand "bud." She has a benign mass on her kidney that her doctors believe was congenital. No doctor has linked that mass to thalidomide exposure.

27. Mary's mother, Margaret McPartlan, suffered from severe morning sickness during the early stages of her pregnancy, so her OB-GYN, Dr. James Ryan, provided her with samples of medication. He did not tell her the name of the drug. Margaret took only one pill. It is now known that Richardson-Merrell employed at least two "detailmen" to promote thalidomide in the Manhattan area.

28. When Mary was born, Dr. Ryan told Margaret that Mary looked "just like" the baby his own wife had recently delivered. Dr. Ryan offered to adopt Mary, an offer her mother declined. Some months later, her mother had Mary out in a baby carriage, and a neighbor greeted them, but mistook Mary for a neighborhood baby named Susan, who had very similar injuries. Susan's father was Dr. Philip Reisman, who soon became Margaret's primary care physician. Dr. Reisman could not tell Margaret what caused their daughters' birth defects, though the two conferred regularly on the subject to try to determine the similarities between the two cases. Margaret had heard about thalidomide and asked Dr. Reisman whether that could be the cause, but Dr. Reisman did not draw that conclusion and did not suggest that thalidomide was responsible for the two girls' injuries. In fact, Dr. Reisman treated Margaret for many years and

treated Mary herself until she was 18, but he never indicated what he believed to be the cause of Mary's injuries.

29. Margaret had retained the pills Dr. Ryan prescribed to her, and her sister, who was a nurse, arranged for the pills to be tested at a nearby lab. The lab lost the pills, and Margaret never learned the results of the analysis.

30. Dr. Reisman counseled Margaret to take Mary to the Rusk Institute of Rehabilitation Medicine at New York University, which she did. Mary was chosen from among the children being treated at Rusk to be the March of Dimes 1966 poster child for Bronx County. Margaret asked the head of the institute, Dr. Leon Greenspan, what could have caused her daughter's birth defect, and Dr. Greenspan told her that Mary simply had a "malformation of the left hand." That is how the family referred to her injury thereafter. Dr. Greenspan never suggested that thalidomide could have caused Mary's injury.

31. When Mary was 33 and pregnant with her first child, she was told by her physician, Dr. Klima, that she appeared to have a thalidomide injury. Mary began to conduct research about her history. She contacted the Rusk Institute to locate the records of the March of Dimes children, but the Institute had not retained any. She contacted the March of Dimes and conducted research at the New York City Public Library. Mary's research consistently hit a dead end, as her sources indicated that thalidomide was not sold in the U.S. because Dr. Frances Kelsey had saved U.S. children, leaving only six victims in this country, victims who had already been identified.

32. Moreover, the predominant medical view has held for decades that unilateral and asymmetrical limb reduction defects like Mary's are not caused by thalidomide exposure. Defendants will make that claim in this case. In fact, there are no representative, controlled studies documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including Mary's injuries. Only recently available studies published in medical and scientific journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, Mary can now allege that her injuries were caused by thalidomide.

5. Plaintiff Larry Wicker

33. Plaintiff Larry Wicker was born prematurely in Cincinnati on July 2, 1958, with multiple severe birth defects. He lacks a full range of motion in both shoulders, due to a malformed shoulder girdle. His elbows and wrists are rigid, with very little ability to bend, and his fingers are rigidly flexed. At age eight, he had essentially no motion or rotation in his elbows or wrists. His neck is shortened, and he has no deep tendon reflexes. He now suffers from symptoms of peripheral neuropathy in both hands.

34. Larry's lower body is also severely affected. He was born with bilateral club foot, with both feet firmly flexed inward. His legs are severely twisted and his hips possibly dislocated. After years of trying to straighten his legs with braces, Larry had three surgeries to

amputate both legs in hopes that he would be able to use a prosthetic device. Larry has been confined to a wheelchair or similar device for most of his life.

35. While pregnant with Larry, his mother, Mary Louise Wicker, lost her husband and was suffering severe mental anguish. She also suffered from severe morning sickness. She sought relief from her doctor, who gave her thalidomide, something she told Larry on numerous occasions when he was old enough to understand. Larry went so far as to contact a lawyer, who told him that thalidomide could not have caused his injury because "thalidomide was never here [in the U.S.]." Publicity about thalidomide in the general media indicated (incorrectly, as it turns out) that thalidomide was first provided to American patients no earlier than 1959, shortly after Richardson-Merrell entered into a distribution contract with Grünenthal.

36. Larry's doctors never diagnosed him with a thalidomide injury. Instead, they diagnosed him with arthrogryposis multiplex congenita, a condition that was automatically assumed to be unrelated to thalidomide because it was not among the constellation of injuries typically addressed in the orthodox medical literature dealing with thalidomide injuries. But thalidomide can cause arthrogryposis multiplex congenita, and caused it in Larry Wicker's case.

6. Plaintiff John Marshall

37. Plaintiff John Marshall was born in Jackson, Mississippi, on February 28, 1959. He was born with multiple severe birth defects, including malformed hands and wrists. He had six fingers on both hands but no thumbs on either hand. Both of his legs were turned backwards, and both ankles were malformed. He had six malformed toes on each foot. After years of wearing braces to try to straighten his legs, he had his right leg amputated.

38. John never knew his mother, Thelma Louise King, who left the family shortly after his birth, leaving John to be raised by his father and grandmother. He had no contact with his mother, and she never discussed his birth defects with him. Family members and doctors never told him the cause of his birth defects. When he turned 18, he pressed the doctors at Mississippi Baptist Crippled Children's Clinic for information about the cause of his birth defects, but they gave him no suggestions about possible causes. Further, the publicity about thalidomide circulated in the general media indicated (incorrectly, as it turns out) that thalidomide was first provided to American patients no earlier than February 1959, shortly after Richardson-Merrell entered into a distribution contract with Grünenthal.

39. Last year, John was able to afford his first computer. He researched birth defects and concluded that he looked like pictures of thalidomiders he found online. This motivated him to try to locate his mother, Thelma, to ask if she had taken medication during her pregnancy. He eventually located her and spoke to her on the telephone, at which time she confirmed that during her pregnancy, she was depressed and suffering from morning sickness. She told him that her doctors gave her vitamins and a pill, which they told her had no side effects but would help her sleep. Her doctor, Dr. Lloyd Berrong, was not only a physician at the time of her pregnancy, but also co-owned a local drug store, Cooper Drugs.

40. John's birth defects occurred because his mother ingested thalidomide. But none of John's doctors ever diagnosed him with a thalidomide-related birth defect, and there was no way for him to have known that his mother had taken thalidomide until he spoke to her last year.

7. Plaintiff John Grover

41. Plaintiff John Grover was born in Neptune/Astbury Park, New Jersey, on January 10, 1961. He suffers from severe birth defects, including a malformed and shortened right arm, as well as a webbed and malformed right hand. His right thumb is present but malformed, permitting only a limited range of motion. He is missing the pectoral muscle on the right side of his body. He has severe and painful curvature of the spine and has suffered from numerous gastrointestinal problems throughout his life. John has been unable to father children. He also suffers from abnormal gum recession, from extreme swelling in his legs, and from peripheral neuropathy in his feet and legs, and was told for the first time in 2010 by his dentist and his neurologist that these conditions were related to thalidomide exposure.

42. John's mother, Hilda, suffered from nervous anxiety and morning sickness during her pregnancy, and was given thalidomide by her physician, Dr. Viccarro, who gave her the drug in his office. But when John was born with multiple birth defects, Dr. Viccarro told Hilda that his injuries were "just a birth defect," suggesting that they may have occurred because of the way that John was lying insider her womb. John's surgeon, a Dr. Ryan, asked Hilda if she thought the thalidomide had caused John's injuries but did not volunteer that opinion himself. Hilda contacted a drug manufacturer on the telephone to ask whether thalidomide could have caused John's injuries, but was told that "sometimes you just get birth defects; we aren't responsible."

43. While John's doctors periodically have made casual comments suggesting that his hand injury may be thalidomide-related, the predominant medical view for decades has held that unilateral and asymmetrical limb reduction defects like John's are not caused by thalidomide

exposure. Defendants will make that claim in this case. In fact, there are no representative, controlled studies documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including John's injuries. Only recently available studies published in medical and scientific journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, John can now allege that his injuries were caused by thalidomide.

8. Plaintiff Sharon Anderson

44. Plaintiff Sharon Anderson was born on April 30, 1960, at the hospital on Tyndall Air Force Base near Panama City, Florida. She suffered from multiple birth defects, including kidney-tube blockage and a left arm that extends to only three inches below the elbow. Sharon has no fingers or hands on her left side, nor does her shoulder rotate correctly on that side. She also has such severe scoliosis that her doctors have recommended that her right hip be replaced.

45. From the time she was in fourth grade, Sharon was raised by her grandparents, and she had little contact with her mother, Barbara, until she was a young adult. As a young adult, she asked her mother about her birth defects. Barbara said that when she was pregnant with Sharon, she suffered from such severe morning sickness that she was forced to quit her job. She consulted a doctor at the base hospital and was told to take medicine, but Barbara did not know the name of the medicine; in those days, medicines were often identified by number and not by name. When Barbara gave birth to Sharon, she asked that same doctor what could have

caused Sharon's birth defects and was told that sometimes "these things just happen." The doctor never suggested that thalidomide caused or might have caused Sharon's birth defects. Sharon recalls that in her childhood, her grandmother had remarked that while pregnant, her mother had taken a drug made "by a German company."

46. In recent years, Sharon has done internet research to learn more about her birth defects. After doing several searches for birth defects caused by drugs in the 1960s, she noted that several of them discussed thalidomide. But Sharon was unable to find any information about U.S. victims or any U.S. distribution of the drug. Her efforts to obtain medical records from the military were fruitless; she was told the records had burned in a fire. In December 2009 or early 2010, Sharon eventually located an association of Canadian thalidomiders, from whom she learned about the litigation being pursued in Australia and the United States.

47. It is not surprising that no doctor has ever told Sharon that thalidomide caused her birth defects, because the predominant medical view has held for decades that thalidomide does not cause unilateral and asymmetrical limb reduction defects like Sharon's. Defendants will make that claim in this case. In fact, there are no representative, controlled studies documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including Sharon's injuries. Only recently available studies published in medical and scientific

journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, Sharon can now allege that his injuries were caused by thalidomide.

9. Plaintiff Diana Cabcabin

48. Plaintiff Diana Cabcabin was born at Bethesda Naval Hospital in Maryland on October 13, 1960. She suffers from multiple birth defects, including a clubbed right foot, missing metatarsals, and diminished musculature in her right leg.

49. Diana's mother suffered from health problems and had a nervous breakdown when Diana was a child. The subject of her birth defects was rarely discussed. Although Diana knows that her mother suffered from morning sickness during her pregnancy and was given a drug for that problem, her mother never told her the name of the drug and may not have known it, as she was Filipino and spoke very little English. Instead, her mother, who was Catholic, simply told her that her birth defects were an act of God.

50. From time to time, Diana would ask her doctors if they had ever seen people with birth defects like hers. Though none of these doctors ever informed Diana that thalidomide caused or could have caused her birth defects, she recalls that on one or two occasions her doctors told her that her birth injuries reminded them of some of the injuries associated with thalidomide exposure. But Diana did not know what thalidomide was or what that meant.

51. A few months ago, Diana was in a carpool of women going on a meditation retreat, and the conversation turned to her birth defects. She mentioned that her mother had taken some sort of a drug during her pregnancy, and one of the women, who was English,

explained how many English babies had been injured by thalidomide. This was the first real understanding that Diana had that thalidomide can cause birth defects

52. It is not surprising that none of Diana's doctors diagnosed her with a thalidomide-related injury. For decades, the predominant medical view has held that unilateral injuries like Diana's are not caused by thalidomide exposure. Defendants will make that claim in this case. In fact, there are no representative, controlled studies documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including Diana's injuries. Only recently available studies published in medical and scientific journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, Diana can now allege that her injuries were caused by thalidomide.

10. Plaintiff Tammy Jackson

53. Plaintiff Tammy Jackson was born in Ranger, Texas, on February 24, 1962. She suffers from multiple birth defects, including an abnormally short right arm, which extends only three inches below her elbow. She has no hand or fingers, only small nubs where fingers should be. Tammy also suffers from scoliosis, something she learned recently. She has also begun to suffer from symptoms of peripheral neuropathy.

54. Tammy's mother, Charlotte Daniels, suffered from morning sickness during the early stages of her pregnancy with Tammy. Charlotte consulted Dr. Gold in Brownwood, Texas,

and he gave her samples of medication in his office, informing her that they would help the morning sickness. He did not tell her the name of the drug.

55. Charlotte then moved to Ranger, Texas, where Tammy was born, delivered by Dr. Watkins. She asked him what might have caused Tammy's birth defects, but he had no opinions about the cause of those injuries.

56. Some years later, Charlotte recalled seeing some reports in the media about thalidomide's effects on babies. But she also recalls learning that thalidomide was not available in the U.S., due to the FDA's refusal to license the drug.

57. When Tammy was pregnant with her first child, there was concern that the baby might be born with birth defects. Her mother assured her that this would not happen because she believed that Tammy's injuries had been caused by the drug she took during pregnancy. Shortly after the baby's birth, Tammy recalls that Charlotte told her that the drug she believed she had taken was thalidomide. Even though her mother had learned that thalidomide was not available in the U.S., Tammy has informed doctors that she believes that her birth defects were caused by the drug.

58. Though Charlotte had become aware of reports that thalidomide was not available in the U.S., she learned differently in about 2000, after gaining access to the Internet. In light of that information, she tried to obtain her medical records but was unable to acquire them.

59. The predominant medical view has held for decades that unilateral and asymmetrical limb reduction defects like Tammy's are not caused by thalidomide exposure. Defendants will make that claim in this case. In fact, there are no representative, controlled

studies documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including Tammy's injuries. Only recently available studies published in medical and scientific journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, Tammy can now allege that her injuries were caused by thalidomide.

11. Plaintiff Carolyn Sampson

60. Plaintiff Carolyn Sampson was born on March 28, 1962, at All Souls Hospital in Morristown, New Jersey. She was born with multiple birth defects, including a malformed left arm that was shorter than a normal arm and lacked an elbow, and a left hand that had only three fingers and no thumb. Her right arm had an enlarged radial head and her elbow was dislocated; her right hand had four fingers but no thumb. She suffered from scoliosis, and her shoulder blades are misaligned. In later years, Carolyn learned that she had a misshaped uterus and a grossly underdeveloped ovary. She also understands that her kidneys may be malformed. She has also learned that because her wrists are abnormally small, they trap the nerves, causing carpal-tunnel-like symptoms. She has begun to suffer from numbness and tingling in her fingers.

61. During the early part of her pregnancy, Carolyn's mother, Marilyn, suffered from headaches and nausea. Ordinarily, she would have taken Alka Seltzer for her headaches, but she was concerned that it might not be safe for her baby. She consulted her doctor, who instead gave

her some medication. When Carolyn was born with multiple birth defects, Marilyn asked her doctor what might have caused the problems, and he told her that some babies are just born with birth defects and that he didn't know the cause. Sometime later, one of Carolyn's pediatricians mentioned to Marilyn that Carolyn resembled some thalidomide babies, but Marilyn did not know what that meant and had no reason to think that she had taken thalidomide.

62. Carolyn heard about thalidomide when she was 17 years old, when a man on a bus told her "you must be a thalidomide baby." Carolyn did not know what a thalidomide baby was, so she asked her mother. While Marilyn told Carolyn that she'd taken medication during her pregnancy, Marilyn couldn't say that it was thalidomide and never suggested that thalidomide could have caused Carolyn's birth defects. Instead, Marilyn counseled Carolyn, as she always had, that she had birth defects because "that is how God made you." Her mother also believed – and told Carolyn – that a "fender bender" car accident that she had while pregnant might have had something to do with Carolyn's injuries.

63. Carolyn took further investigatory steps as a young adult, but her research took her to one dead end after another. She contacted a lawyer, who attempted to obtain her medical records, an effort that was ultimately fruitless. Though the doctor initially informed Carolyn's lawyer that he had kept all of his records, upon learning *whose* records were being requested, he said that "those records are lost." Her mother had retained one pill, which the lawyer sent to a lab when Carolyn was about 20. The lab informed her that the pill was "too old" to identify.

64. Carolyn also researched historical information about thalidomide but learned that it was never on the market in the U.S. Carolyn had people tell her that she couldn't have a

thalidomide injury because it was never approved in the U.S. This research caused Carolyn to conclude that thalidomide could not possibly be the cause of her birth defects; she believed she had hit a dead end. Her lawyer declined to file a case for her. At no point in Carolyn's life has any doctor told her or her mother that thalidomide caused or could have caused her birth defects.

65. In early September 2011, Carolyn conducted an internet search in preparation for writing an article about her experiences as a person with birth defects, including her parents' reluctance to ever talk openly about what had happened. She was hoping to find accounts of other people with birth defects, people whose experiences might have been similar to hers. It was during this search that she learned for the first time that Defendants had given thalidomide to more than 1200 U.S. doctors; those who had repeatedly told her that thalidomide was not present in the U.S. were wrong. Armed with this knowledge, Carolyn can now allege that her injuries were caused by thalidomide. Carolyn promptly followed up with the FDA, asking the agency to provide her with that list of 1200 doctors. But the FDA refused to disclose it, contending that the list of doctors was "proprietary."

12. Plaintiff Ted Mann

66. Plaintiff Ted Mann was born on September 13, 1962, in New Brunswick Hospital, Raritan, New Jersey. He was born with serious birth defects, including a malformed left arm and shoulders, a missing pectoral muscle, and a malformed left hand. The fingers on his right hand are webbed. Years later, he learned he had a defect in his spine, necessitating surgery.

67. Ted's mother, Gail, suffered from morning sickness during her pregnancy. She consulted her doctor, Dr. Levine, who gave her pills in his office. Gail believed that those pills

were prenatal vitamins and has consistently maintained throughout Ted's life that she took vitamins, not thalidomide.

68. When Ted was born with birth defects, Gail recalls discussing his injuries with Dr. Levine, who told her that Ted had developed these problems because of the way he had been laying inside her womb. This is what Gail has always believed, and this is what she has always told Ted.

69. When Ted was about 17 years old, his paternal uncle (now-deceased) told him "out of the blue" that his mother had taken thalidomide, causing Ted to mention to others that he believed that he might be a thalidomider. But his mother has consistently denied taking the drug. And in 2008, a physician told him that he was too young to be a thalidomide victim and that, in any case, thalidomide had not been distributed in the U.S. This opinion was reinforced in 2010, when Ted contacted people he believed to be experts on thalidomide and the injuries it causes – the staff at the UK Thalidomide Trust. Ted asked whether his injuries appeared to be thalidomide-related and, in the summer of 2010, the executive director of the trust informed Ted in no uncertain terms that his injury was not thalidomide-related. The executive director also told him that thalidomide was simply not distributed in the U.S. during the time that Ted's mother was pregnant, suggesting instead that a chemical like cadmium might have caused Ted's injuries.

70. Unknown to Ted, neither his doctor nor the staff of the UK Thalidomide Trust was correct about the timing and extent of thalidomide distribution in the U.S. And while the staff of the UK Thalidomide Trust certainly adhered to the predominant medical view which has

held for decades that unilateral or asymmetrical limb reduction defects like Ted's are not caused by thalidomide exposure, recently available studies published in medical and scientific journals reveal the flaws in this school of thought.

71. In October 2011, Gail's mother and her sister Marie were discussing the issue of Ted's birth defects, and Marie informed Gail that she clearly remembered that Gail had taken thalidomide during her pregnancy with Ted. Marie reminded Gail that the two of them had discussed the matter at the time, during the pregnancy, and reminded her that they were both being treated by the same man, Dr. Levine. This was Ted's first reliable confirmation that his mother had taken thalidomide. Armed with this knowledge, Ted can now allege that his injuries were caused by thalidomide.

13. Plaintiff Richard Anderson

72. Plaintiff Richard Anderson was born on February 15, 1962, at Elmhurst Hospital in Queens, New York. Richard was born with serious birth defects, including scoliosis and an abnormally short left arm with a fixed elbow and a shoulder that does not function normally. The left side of his chest is smaller than his right. The fingers on the left hand are shriveled and useless, with a withered fifth finger and an abnormally small thumb.

73. Richard's parents never told him that his mother took thalidomide. Though Richard has asked doctors throughout his life about the cause of his injuries, he has never been given an answer. But in recent years, a nurse suggested to Richard that his injury was like those suffered by thalidomide babies. Some months later, Richard was reading a Larousse medical dictionary and saw pictures of people with thalidomide injuries. These events provided Richard

with his first clue that his injuries are thalidomide-related. Still, no family members could tell him that his mother had taken thalidomide, and Richard had no knowledge about the companies that made thalidomide. No doctor had ever told Richard that thalidomide caused or could have caused his injuries.

74. Richard began conducting research on his own, seeking information from the Long Island University International Drug Information Center, Arnold and Marie Schwartz College of Pharmacy and Health Sciences. They alerted him to the fact that defendant Grünenthal had developed and manufactured the drug for distribution in this country, and advised him to write to the company, which he did. He wrote to Grünenthal but received no information that he could use to determine whether the drug had been provided to doctors in his area, or whether his injury was related to thalidomide. The FDA will not release the list of doctors who received thalidomide from Richardson-Merrell

75. On July 18, 2011, Richard was evaluated by a Dr. Johnson, who informed him for the first time that thalidomide caused the damage to his left hand.

76. It is not surprising that Richard was not told that until 2011 that his injuries were caused by thalidomide. The predominant medical view has held for decades that unilateral and asymmetrical limb reduction defects like Richard's are not caused by thalidomide exposure. Defendants will make that claim in this case. In fact, there are no representative, controlled studies documenting the true spectrum of thalidomide injuries. The thalidomide syndrome has only been defined in a piecemeal fashion from fragmentary reports in the medical literature synthesized to produce a range of classical injuries that suit a preconceived theory of the

mechanism of the drug. Until recently, a universe of thalidomide related injuries has been thereby excluded from diagnosis, including Richard's injuries. Only recently available studies published in medical and scientific journals reveal the flaws in the orthodox medical opinion. Armed with this knowledge, Richard can now allege that his injuries were caused by thalidomide.

B. Defendants

1. SmithKline Beecham Corporation

77. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline is a successor to Smith, Kline & French ("SKF"). SmithKline Beecham Corporation is a Pennsylvania corporation with a principal place of business in Philadelphia County, a status it has held since its original incorporation in this county in 1929 as the Smith, Kline & French Corporation. Since the early 1800s, SmithKline Beecham Corporation and its predecessors have continuously sold pharmaceutical products and prescription drugs in Pennsylvania, and maintained their principal place of business in Philadelphia County. To that end, SmithKline Beecham Corporation and its predecessors have engaged in research (including clinical trials and testing), product development, manufacture, production, promotion, distribution, and marketing of prescription drugs and over-the-counter products for distribution, sale, and use by the general public throughout the United States. On October 27, 2009, SmithKline Beecham Corporation filed articles of dissolution with the Pennsylvania Secretary of State's office. Under 15 Pa. C.S. § 1979, SmithKline Beecham Corporation continues to be a citizen of Pennsylvania for two years after dissolution.

2. Defendant GlaxoSmithKline LLC

78. Defendant GlaxoSmithKline LLC ("GSK LLC") is a Delaware limited liability corporation, with a principal place of business in Pennsylvania. Since 2009, GSK LLC has been engaged in research (including clinical trials and testing), product development, manufacture, production, promotion, distribution, and marketing of prescription drugs and over-the-counter products for distribution, sale, and use by the general public throughout the United States. GSK LLC alleges that it succeeds to the liabilities of SmithKline Beecham Corporation.

3. Defendant GlaxoSmithKline Holdings, Inc.

79. Defendant GlaxoSmithKline Holdings, Inc. ("GSK Holdings") is a Delaware corporation with a principal place of business in Philadelphia County, Pennsylvania. GSK Holdings is a holding company and a member of GSK LLC. Upon information and belief, GSK Holdings is a sham corporation formed to create diversity in Pennsylvania-filed cases and prevent courts of the Commonwealth of Pennsylvania from exercising jurisdiction over the Philadelphia-based pharmaceutical business and activities of SmithKline Beecham/GSK LLC. Plaintiffs will refer to defendants SmithKline Beecham Corporation, GSK LLC, and GSK Holdings collectively as the "Glaxo Defendants."

4. Defendant Sanofi-Aventis, U.S., LLC

80. Defendant Sanofi-Aventis, U.S., LLC ("Sanofi") is a Delaware corporation with a principal place of business in Bridgewater, New Jersey. Sanofi is the legal successor to the liabilities of the William S. Merrell Company, National Drug Company, and Richardson-Merrell, Inc., the North American licensee/distributors of thalidomide. Sanofi and its predecessors are or

were pharmaceutical companies engaged in research (including clinical trials and testing), product development, manufacture, production, promotion, distribution, and marketing of prescription drugs and over-the-counter products for distribution, sale, and use by the general public throughout the United States. At all times relevant hereto, the William S. Merrell Company, National Drug Company and Richardson-Merrell, Inc., distributed the confirmed teratogenic drug[1], thalidomide, throughout the United States and Canada, including Pennsylvania, causing Plaintiffs to sustain serious birth defects.

5. Defendant Avantor Performance Materials

81. Defendant Avantor Performance Materials is a New Jersey corporation, with its headquarters and principal place of business in Center Valley, Pennsylvania. Upon information and belief, Avantor is the legal successor to the J.T. Baker Company, which has been involved in the business of manufacturing pharmaceutical products in New Jersey since 1904. At all times relevant hereto, J.T. Baker was a subsidiary of Richardson-Merrell, Inc., and, upon information and belief, it manufactured the teratogenic drug thalidomide in New Jersey, distributing the drug throughout the United States and Canada, including Pennsylvania. At times in this Complaint, Plaintiffs will refer to defendants Sanofi and Avantor as the Merrell Defendants.

6. Grünenthal GmbH

82. Grünenthal GmbH is a corporation incorporated under the laws of Germany, with a principal office in Aachen, Germany. Since 1946, Grünenthal has manufactured, sold, and

[1] Teratogen is defined as: "Any agent that can disturb the development of an embryo or fetus. Teratogens may cause a birth defect in the child. Or a teratogen may halt the pregnancy outright. The classes of teratogens include radiation, maternal infections, chemicals, and drugs." http://www.medterms.com/script/main/art.asp?articlekey=11315.

distributed pharmaceutical products worldwide, including in the United States. At all times relevant hereto, Grünenthal designed, developed, patented, manufactured, distributed, marketed, and directed its teratogenic drug, thalidomide, worldwide, including Pennsylvania. Grünenthal continues to distribute its drugs throughout the United States, including Pennsylvania, through licensing partners, such as Johnson & Johnson, Ortho-McNeil, and Endo Pharmaceuticals. As a result, Grünenthal is subject to suit in the courts of the Commonwealth of Pennsylvania.

7. Grünenthal U.S.A., Inc.

83. Grünenthal U.S.A., Inc., is a Delaware corporation with its principal place of business in Bedminster, New Jersey. It is the U.S. subsidiary of Grünenthal GmbH. Upon information and belief, Grünenthal U.S.A. is the alter ego of Grünenthal GmbH. Plaintiffs will refer to defendants Grünenthal GmbH and Grünenthal U.S.A. collectively as the "Grünenthal Defendants."

III. JURISDICTION AND VENUE

84. At relevant times, the Glaxo Defendants' predecessor SKF tested thalidomide in this judicial District, distributed thalidomide to doctors and patients without a warning in and from this District, designed and implemented a non-consensual thalidomide clinical trial from this District, and made material omissions and misrepresentations in this District. SmithKline Beecham Corporation and its predecessors have also engaged in continuous and systematic business activities in this District over a period of more than 100 years. This Court may exercise *in personam* jurisdiction over SmithKline Beecham Corporation consistent with due process and under 42 Pa. C.S.A. 5301(a)(2)(iii) and 42 Pa.C.S.A. 5322.

85. Jurisdiction is proper against GSK LLC as the successor to SmithKline Beecham Corporation, whose predecessor SKF tested thalidomide in this District, distributed thalidomide to doctors and patients without a warning in and from this District, designed and implemented a non-consensual thalidomide clinical trial from this District, and made material omissions and misrepresentations in this District. GSK LLC also owns and operates an established pharmaceutical business in this District, and has continuous and systematic contacts in this District. This Court may exercise *in personam* jurisdiction over GSK LLC consistent with due process and under 42 Pa. C.S.A. 5301(a)(2)(iii) and 42 Pa.C.S.A. 5322.

86. Jurisdiction is proper against GSK Holdings as the sole member of GSK LLC. Its principal place of business as sole member of GSK LLC, which owns and operates an active pharmaceutical business in this District, is in Philadelphia, Pennsylvania, and it has continuous and systematic contacts in this District. This Court may exercise *in personam* jurisdiction over GSK Holdings consistent with due process and under 42 Pa. C.S.A. 5301(a)(2)(iii) and 42 Pa.C.S.A. 5322.

87. Jurisdiction is proper against Sanofi-Aventis as the successor to Richardson-Merrell and its subsidiaries/divisions, the William S. Merrell Company and National Drug Company. At all relevant times, Richardson-Merrell, the William S. Merrell Company and National Drug Company tested thalidomide in this District, distributed thalidomide to doctors and patients without a warning in and from this District, designed and implemented a non-consensual thalidomide clinical trial from this District, and made material omissions and misrepresentations in this District. As one of the nation's largest pharmaceutical/diversified

health care companies, Sanofi-Aventis directs pharmaceutical products (including but not limited to Ambien and Plavix) to Pennsylvania, and this District on a regular and sustained basis, it conducts research and development operations in Pennsylvania, it maintains a research facility in Pennsylvania that employs 350 people in Malvern, Pennsylvania, and 200 field employees, and it receives substantial financial benefits and profits from its business activities in Pennsylvania. This Court may exercise *in personam* jurisdiction over Sanofi-Aventis consistent with due process and under 42 Pa. C.S.A. 5301(a)(2)(iii) and 42 Pa.C.S.A. 5322.

88. Jurisdiction is proper against Avantor Performance Materials as the successor to J.T. Baker Company, a subsidiary of Richardson-Merrell. At relevant times, J.T. Baker Company manufactured thalidomide and distributed it for use in this District, distributed thalidomide to doctors and patients without a warning in and from this District, and made material omissions and misrepresentations in this District. And as of April 2011, Avantor's corporate headquarters have been located in Center Valley, Pennsylvania. Avantor's business activities in Pennsylvania are continuous and systematic, and this Court may exercise *in person-am* jurisdiction over Avantor consistent with due process and under 42 Pa. C.S.A. 5301(a)(2)(iii) and 42 Pa.C.S.A. 5322.

89. Jurisdiction is proper against Grünenthal GmbH because at all relevant times, Grünenthal manufactured thalidomide and purposefully availed itself of the markets in the United States, including Pennsylvania, by intentionally introducing thalidomide into the stream of commerce in the United States and Pennsylvania. Grünenthal purposefully availed itself of Pennsylvania's markets by initially targeting a long-time Pennsylvania corporation, Smith, Kline

& French, to act as its North American distributor, and by contracting with Smith, Kline & French to conduct animal testing and human clinical trials in this state on its behalf. Later, Grünenthal selected Richardson-Merrell as its distributor, knowing and intending that its Pennsylvania-based subsidiary, National Drug Company, would distribute thalidomide in Pennsylvania and elsewhere. Upon information and belief, it was Grünenthal's practice to ship thalidomide directly to the United States, knowing and intending that both Richardson-Merrell and its subsidiaries, including the William S. Merrell Company and National Drug Company would distribute thalidomide in this state. Because Grünenthal GmbH shipped its drug directly to the United States, Grünenthal GmbH knew and intended that its thalidomide products would be sold and distributed from and within the United States and Pennsylvania. Grünenthal GmbH controlled the manner in which its thalidomide products were marketed and distributed in the United States and Pennsylvania, and was jointly responsible for the content of health and safety warnings used in this and other states. Grünenthal GmbH also held the U.S. patent for thalidomide, which provided it with control over the sale and distribution of thalidomide nation-wide. Further, it obtained U.S. trademark protection for its thalidomide drug product Softenon in 1960, and for its company name in 1953. Upon information and belief, Grünenthal GmbH's licensing agreement with Merrell entitled it to between 3% and 10% of net North American sales. Grünenthal GmbH also has continuously and systematically availed itself of markets in the U.S., including Pennsylvania, with respect to its sale and marketing of other drug products to the present day. It has continued to manufacture drug products, including but not limited to tramadol, tapentadol/oxymorphone, and axomadol, and to systematically and continuously ship

those products into commercial markets in the United States and Pennsylvania, acting through joint ventures and licensing agreements. One of Grünenthal's GmbH partnership arrangements was specifically entered into so that it could "take part in events on the US market on short notice." The FDA relies on Grünenthal GmbH's studies in considering New Drug Applications for these drugs, which makes Grünenthal GmbH subject to FDA's Foreign Labs Inspection program. Grünenthal GmbH obtains and holds U.S. patents for drug products; in 2009, almost half the patents awarded to the company were U.S. patents. And as it did with thalidomide and as is its practice, Grünenthal GmbH shares responsibilities for product development and commercialization activities with its licensees, activities that affect how these drugs are marketed and sold in the United States and Pennsylvania. Grünenthal GmbH has continuously received significant and financial benefits from these activities, revenues based on annual total net sales of such drugs. Grünenthal GmbH also conducts pharmaceutical drug clinical trials in the United States and Pennsylvania through its subsidiary, Grünenthal USA, which is, upon information and belief, the alter ego of Grünenthal GmbH.

90. Jurisdiction is proper over Grünenthal USA, because it is a sham corporation and the alter ego of Grünenthal GmbH, so the parent's contacts with the forum are properly imputed to the subsidiary. Upon information and belief, Grünenthal USA is a mere extension of its parent, Grünenthal GmbH, and would not be financially stable or viable on its own. Upon information and belief, the owner of Grünenthal USA is the Wirtz family, including but not limited to Sebastian Wirtz. The Wirtz family also owns and controls the parent company, Grünenthal GmbH. According to court documents submitted by Grünenthal USA, Mr. Wirtz is

and has been a principal of Grünenthal USA. The companies share at least one board member, Dr. Eric-Paul Páques. As Grünenthal USA has alleged in court proceedings, its business is to provide operational and regulatory support for the clinical trials conducted for drugs developed by its parent; of necessity, then, the parent Grünenthal directs and controls the support activities undertaken by Grünenthal USA. Grünenthal USA has no independent public internet presence; instead, contacts with the company are directed to Grünenthal GmbH. Grünenthal GmbH's privacy policies are applied to Grünenthal USA online contacts. Grünenthal USA is merely a liability shield created by Grünenthal GmbH in hopes of conducting clinical trials on U.S. citizens without accountability for those activities. Jurisdiction is also proper based on Grünenthal USA's own activities. Grünenthal USA has continuous and systematic contacts with Pennsylvania because, upon information and belief, it regularly conducts clinical trials for drug products in Pennsylvania and has obtained funding from the Commonwealth of Pennsylvania for such trials. Grünenthal USA also holds trademark rights for a variety of drug products, including Abiantem, Guard, HM-Guard, Morphiguard, and Ixibaren.

91. Venue is proper because SmithKline Beecham's principal place of business is in Philadelphia, as are the principal places of business for both Glaxo Defendants. And, Avantor's headquarters is located in Center Valley, Pennsylvania. In addition, SmithKline Beecham has conducted its pharmaceutical business in Philadelphia for more than 100 years. SmithKline Beecham and its predecessors tested thalidomide in this District, distributed thalidomide to doctors and patients without a warning in and from this District, designed and implemented a non-consensual thalidomide clinical trial in this District, and made material omissions and

misrepresentations in this District so as to subject it to *in personam* jurisdiction in this District. Venue is proper in this District as to all Defendants under Pa. R. C. P. No. 2179 and 1006(c).

IV. STATEMENT OF FACTS

A. An overview of the thalidomide tragedy.

92. Administering thalidomide to pregnant women has been called one of the biggest disasters in modern medicine. First sold in Germany as an over-the-counter remedy for everything from the flu to insomnia to morning sickness, the drug was advertised as "completely harmless" and "atoxic" during the nine years that it was distributed for human use. Far from being harmless, the ingestion of even one pill during the early stages of pregnancy caused severe birth defects, including malformed limbs, curved spines, malformed or missing internal organs, and damaged ears, eyes, and gastrointestinal systems.

93. The tragedy starts with Grünenthal, a German company that was a subsidiary of a large cosmetics company. Its research was unashamedly market-driven, and its corporate strategy was to penetrate the burgeoning antibiotic boom. Conditions in postwar Germany were appalling, and health authorities feared epidemics of tuberculosis and even cholera. So antibiotics were big business for German pharmaceutical companies. The director of Grünenthal's research and development group was Dr. Heinrich Mückter.

94. Two years before he joined Grünenthal, Mückter was a medical scientist for the army of the Third Reich. Specifically, he was Medical Officer *(Stabsarzt)* to the Superior Command of the German Occupation Forces occupying Krakau, Poland, with the additional, ominous title of "Director for the Institute of Spotted Fever and Virus Research." Given the role

that military medicine played in the objectives and methods of the Nazi occupation of Krakau, Mückter's work there involved the science of killing rather than healing.

95. Within a year at his first civilian job, Mückter succeeded in producing penicillin from mold cultures, and thereby boosted Grünenthal into the limelight: it became the first company in West Germany to be allowed by the Allied military government to produce penicillin industrially. By 1950 they were producing the drug in both oral and injectable form.

96. In the race to find new antibiotics, it wasn't long before Grünenthal became notorious for rushing drugs to market with inadequate testing. Between 1953 and 1954, the company developed an antibiotic they called Supracillin, a variant of streptomycin. Though powerful, streptomycin is also highly toxic: the drug may damage nerves between the inner ear and the brain, resulting in deafness. Grünenthal claimed they had completely eliminated these side effects with Supracillin, a claim that later proved untrue. The company also developed another antibiotic, Pulmo 550, which, they claimed, was superior to penicillin. But Grünenthal had ignored reports of severe side effects, and was later harshly reprimanded for using this antibiotic in humans before testing it thoroughly in animals.

97. Grünenthal began testing the use of thalidomide as a sedative. Based on minimal scientific research, and even though it did not sedate animals, Mückter decided to try it as a sedative in humans. Grünenthal handed out pills to their employees. As one observer put it, "Thalidomide was introduced by the method of Russian roulette. Practically nothing was known about the drug at the time of its marketing." Exactly why Grünenthal acted so irresponsibly is

unknown but the damaged medical world of postwar Germany – the "cradle of thalidomide" – suggests that the lingering callousness of medicine under the Third Reich played a role.

98. On October 1, 1957, thalidomide was first released as a sedative under the patent name Contergan. Because of its unambiguous claims of safety, thalidomide was sold over the counter in Germany, and later in other countries as well. The marketing campaign was massive. Grünenthal advertised the new drug in fifty medical journals, sent out 50,000 "therapeutic circulars," and mailed 250,000 personal letters to individual physicians, emphasizing the drug's safety. The main thrust of the campaign was that, unlike other sedatives currently on the market, thalidomide was completely safe. Even a determined suicide could not take enough Contergan to cause death. Furthermore, accidental overdoses by children would be unheard-of with this drug, a claim later substantiated by actual cases that were widely publicized by the company.

99. In the world market, thalidomide was sold separately under at least thirty-seven names. It was also combined with a number of other drugs, including aspirin, quinine, and even barbiturates. In several countries it was available by prescription only, but in Germany and other countries it was sold over the counter. Alone or in combination, thalidomide was used for colds, coughs, flu, asthma, headaches, anxiety, and, of course, sleeplessness. Later, when birth defects began to appear, the multiple drug names, the combinations, and the absence of prescriptions made it very difficult to establish the cause of the epidemic. Thalidomide was considered so safe that many women didn't bother to list it among drugs they had taken during pregnancy.

100. The only major country that had not yet been penetrated by the 1950s was the United States, and Grünenthal executives were eager to crack that enormous market. But when

they proposed distributing thalidomide to Smith, Kline & French – a company with much more experience in research – the pharmaceutical giant tested the drug in animals and declined to consider it further for reasons that have been concealed for decades. Grünenthal approached several other U.S. pharmaceutical companies without success. Finally, in October 1958, the company signed a contract with the 134-year-old William S. Merrell Company of Cincinnati to market thalidomide throughout the United States (sharing the Canadian market with Frank W. Horner, Ltd. of Montréal, which sold the drug under the brand name Talimol). On September 8, 1960, Richardson-Merrell (as it was then known) submitted an application to the U.S. Food and Drug Administration to market thalidomide throughout the United States.

101. About a year after thalidomide became available to the general public outside the United States, complaints of side effects began trickling in to Grünenthal, which shrugged off these early notices.

102. During the following year, thalidomide sales increased dramatically. So did the reports of side effects. Complaints included dizziness, decreased blood pressure, hangover, memory loss, constipation, trembling, cold hands and feet that slowly turned numb, and allergic reactions. Many of these symptoms had been seen–and ignored–in the clinical trials.

103. In October 1959, Dr. Ralf Voss, a Düsseldorf neurologist, wrote to Grünenthal asking if anyone had reported that thalidomide caused polyneuritis, a numbness and tingling in the hands and feet: a 63-year-old patient who had been using thalidomide regularly for a year and a half was exhibiting such symptoms. Drs. Heinrich Mückter and Günther Sievers wrote back that they had received no such complaints. That was a deliberate, bold-faced lie.

104. A new phenomenon began to appear across Germany. Physicians were seeing cases of a birth defect so rare that most had never encountered anything like it. In December 1959, a Dr. Weidenbach presented the case history of a one-year-old girl. The baby's arms and legs were so reduced that the hands and feet were attached directly to the body. This condition is known as terra-phocomelia (literally, "four seal's limbs.") Weidenbach felt that this case must be genetic. Though not completely unknown, this type of defect was extremely rare; there were only a handful of cases in the literature, and a Danish study in 1949 had estimated that phocomelia occurred in 1 out of 4 million births. Still, a few other physicians had seen similar cases in Germany.

105. Unusual birth defects of this nature were being observed in other countries. Here in the United States an application was submitted to the FDA on September 8, 1960, by Richardson-Merrell. Richardson-Merrell executives were prepared to release the drug on March 6, 1961, and engaged in a massive pre-FDA approval promotional campaign. The campaign recommended thalidomide for anxiety associated with a fantastic variety of conditions that included abdominal pain, alcoholism, anorexia, asthma, cancer, cardiovascular disease, dental procedures, emotional instability, functional bowel distress, kidney disease, marital discord, menopause, nausea and vomiting, nervous exhaustion, nightmares, poor school work, premature ejaculation, and tuberculosis.

106. Richardson-Merrell had begun distributing thalidomide in the United States for "clinical trials" a year and a half before their FDA application, *and expanded the trials three months later to include pregnant women.* This "investigational program" was not even

organized by the company's medical department, as was usual, but instead by the sales and marketing division.

107. Richardson-Merrell might have conducted cautious experiments with small samples of carefully monitored subjects. Instead, they carelessly distributed more than 2.5 *million* tablets to approximately 20,000 patients, handed out by 1,267 physicians; the pills, of different colors and sizes, were distributed in envelopes or boxes marked only with the directions for use. This was dramatically larger than any previous drug trial conducted in the United States. The FDA later estimated that 3,760 women of childbearing age took the drug, of whom 207 were known to be pregnant. And it only took one tablet at the wrong time to cause horrendous birth defects.

108. Internally, Richardson-Merrell made it clear these were not clinical trials: The company's Hospital Clinical Program noted: "Bear in mind, these are not *basic* clinical research studies. We have firmly established the safety, dosage, and usefulness of Kevadon by both foreign and U.S. laboratory and clinical studies. This program is designed to gain widespread *confirmation* of its usefulness in a variety of hospitalized patients." Doctors "need not report results if they don't want to .... We may send them report forms or reminder letters, but these are strict reminders and they need not reply."

109. Many of the participating physicians did not even record the names of patients who had taken thalidomide, much less their response to it, and the company even failed to make note of all the doctors to whom they had sent samples.

110. As reports of birth defects around the world could no longer be suppressed, Grünenthal withdrew thalidomide from the market.

111. Richardson-Merrell withdrew its application from the FDA on March 8, 1962, and removed it from the Canadian market – but only after the government in Ottawa demanded it. The company also informed the FDA that they were notifying physicians connected with Richardson-Merrell in the U.S., warning them of the possible dangers from thalidomide. The FDA scientist involved with the application observed that the FDA began "to think it might have been more widely used in this country than we had gathered from the new drug application, so we asked for a complete list of the doctors they had sent the drug to, and were very surprised at the numbers involved." Many of these physicians later claimed never to have received the letters, and most had not kept track of which subjects had taken the drug, so they could not even warn the patients of the potential danger.

112. In the absence of doctors' records, it can never be known how many babies died or were injured in the U.S. because of thalidomide's "clinical trials."

113. On July 23, 1962, an FDA inspector visited Richardson-Merrell Co., trying to find how much thalidomide still remained unaccounted for in the U.S. Altogether, two tons of the material were never found. The inspector later commented, "I cannot help but have doubts about the adequacy and effectiveness of the [recall] procedures followed, since no formal letter was used (by the drug company), no material was returned, and Richardson-Merrell has no record or information as to how much material was destroyed or who destroyed it, if any."

114. The tragedy of thalidomide unfolded before a world aghast with horror.

115. For many people, the simple, unspeakable word that came to mind at the sight of a disintegrated victim was "monster." In fact, the word teratogenic in ancient Greek meant "monster-making." The stunted, mangled limbs of the infants, whose photographs appeared in the press, suggested nothing so much as nature gone wrong, again and again. Many people recoiled from the sight of a thalidomide victim, insisting that this should not even be possible. It threatens our simplest sense of order, and vocabulary: is that . . . a hand? Is it polite to use the word "flipper"? (It is not, in ordinary conversation; but it is the word used in scientific discussion.) Is that still called a thumb if it has three joints? (It is.) This is a nightmare in flesh and blood. It is real, and it threatens us, by reflecting sunlight into the darkest comers of our fearful vulnerability. The sight of these babies' bodies, mangled as if by chemical shrapnel, proved unbearable to many, and not only strangers; nurses, doctors, and other health care providers as well as family members often turned away in revulsion from the victims, some of whom were happy babies, gurgling and cooing, wide-eyed, like most other infants.

116. These children posed puzzles about elementary medical practices that baffled even the most compassionate doctors. How, for example, do you monitor the blood pressure of an infant who has no arms or legs? What is a normal reading for that child? And. when does a rising temperature threaten an infant who cannot disperse heat from the limbs?

117. "I have never seen such a reaction among my staff as when they were faced with thalidomide children," said Dr. Gerard Vaughan of Guy's Hospital, London. "They were horrified. I had great difficulty in getting them to carry out a psychological test or exam."